

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Brien E. Pierpont et al.
SERIAL NO.: 10/773,925
FOR: ANGIOPLASTY METHOD AND MEANS FOR
PERFORMING ANGIOPLASTY
FILED: February 6, 2004
Group/A.U.: 3763
Conf. No.: 8476
Examiner: Laura A. Bouchelle
Docket No.: P06547US1

Mail Stop Reply Brief - Patents
Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

REPLY TO EXAMINER'S ANSWER

This brief is submitted in response to the Examiner's Answer of March 3, 2009 and pursuant to 37 CFR § 41.41 in furtherance of the Appeal Brief submitted for this application on October 28, 2008, and Notice of Appeal submitted on September 30, 2008.

Certificate of Electronic Transmission

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office via EFS-Web (United States Patent and Trademark Office's web-based patent application and document submission) on this 18th day of March 2009.

Timothy J. Zarley

REMARKS

Claims 1 - 13 continue to be rejected under 35 U.S.C. § 103 as being unpatentable over Pierpont in view of Crittenden. Appellant continues to assert that a prima facie case of obviousness has not been provided because a combination of the prior art references would not result in the invention as claimed in independent claims 1 and 9.

Both independent claims 1 and 9 require an elongated treatment catheter extending through an opening in the tubular wall of an anchoring catheter. Although in the Examiner's Answer, the Examiner recognizes that "Crittenden does not specifically teach extending a treatment catheter through the sidewall of an anchoring catheter" the Examiner asserts that the rejection is proper because Crittenden teaches the general concept of inserting one member through the sidewall of another member. (See Examiner's Answer, page 4, 3d paragraph - page 5, 2d paragraph). Appellant respectfully asserts that the Examiner's basis for maintaining the obviousness rejection is incorrect, as the Examiner is relying on generalities and characterizes the Applicant's claims in an oversimplified manner. In response to the Examiner's assertion, Applicant's claims are not directed to inserting any one member through the sidewall of any other member, Applicant's claims are directed to inserting a treatment catheter through an opening in the tubular wall of an anchoring catheter. Applicant's disclosure is specifically directed to overcoming problems associated with the loading and positioning an anchoring catheter during an angioplasty procedure. (Applicant's disclosure, paragraphs [004 - 006]). The claims are directed

to a very specific set of elements having specific limitations, and overcome the problems in the art by providing an opening in the side wall of an anchoring catheter so that a guidewire and balloon dilation/treatment catheter and guidewire may extend therethrough. (Applicant's disclosure, paragraphs [004 - 006]). The cited references provide no disclosure of these elements required by Applicant's claims. Although the Pierpont reference discloses an anchoring catheter, Pierpont does not disclose an anchoring catheter having an opening in its side wall which receives a guidewire and treatment catheter. (See generally, Pierpont). Crittenden does not provide any teaching of an anchoring catheter whatsoever, and instead is directed to an angioplasty procedure utilizing only a single catheter and a guidewire. (See generally, Crittenden). Therefore, because Applicant's claims are not directed to broadly covering the insertion of any one member in any other member, and the references do not cover the specific elements contained in Applicant's claims, Applicant asserts that the general teachings from the Pierpont and Crittenden reference cannot form the basis of a *prima facie* case of obviousness.

Appellant additionally continues to assert that claims 1 and 9 are non-obvious because there would be no reason to combine the Pierpont and Crittenden references, and the combination of the references is a product of hindsight reasoning. The Examiner asserts that the combination of Pierpont and Crittenden is not the product of hindsight reasoning. Recognizing that the test for making a combination to teach obviousness is given both of the references, whether one of ordinary skill in the art would

reasonably make the combination, the Examiner asserts that "[i]t is reasonable to expect that when searching for a device that is concerned with advancing a balloon dilation treatment catheter. . .one would look to devices concerned with advancing guidewires through catheter[s]." (See Examiner's Answer, page 4, 3d paragraph - page 5, 2d paragraph). Appellant once again respectfully asserts that the Examiner's assertions are based upon oversimplified and generalized characterizations of the prior art references and the problem that Applicant's invention seeks to overcome. Although those of ordinary skill in the art were aware of the general teaching of advancing guidewires through catheters, those skilled in the art did not consider the general teaching of inserting a guidewire into the side of a dilation catheter applicable to securing a guiding catheter in a fixed position or providing an opening in the side wall of an anchoring catheter. While Pierpont is concerned with advancing a balloon dilation treatment catheter, advancement is achieved by securing the guiding catheter in a fixed position. (Pierpont, col. 1, line 51 - col. 2, line 5, specifically, Col. 1, line 67 - col. 2, line 2: "When the guiding catheter remains in a fixed position, it facilitates immensely the ability to advance the balloon dilatation catheter.").(emphasis).

Crittenden is not directed to securing a guiding catheter in a fixed position, as Crittenden provides no such disclosure; Crittenden is instead concerned with providing the ability to exchange guidewires in an indwelling catheter, and overcoming the problems associated with guidewires such as entanglement of multiple guidewires and damaging the inner

surface of the artery. (Crittenden, col. 2, lines 3 - 16). Applicant, as one of advanced skill in the art (as asserted by Appellant in the appeal brief), would not and did not simply look to devices concerned with the general teaching of advancing/inserting guidewires through catheters (as asserted by the Examiner) as being applicable to secure a guiding catheter in a fixed position or to provide an opening in the side wall of an anchoring catheter through which a guidewire and balloon dilation/treatment catheter may extend. In fact, Applicant was indeed aware of the general teaching of advancing/inserting guidewires through catheters, as provided in paragraph [005] of Applicant's Specification:

Known in the art are a variety of means for inserting a guidewire through the side of a balloon dilatation catheter. Examples of such devices are disclosed in U.S. Pat. Nos. 5,489,271 and 5,554,118. While these devices assist in inserting or exchanging a balloon dilatation catheter, they do not incorporate the use of or the advantages associated with the use of an anchoring catheter to maintain the position [e.g., the securing] of the guidewire, the balloon dilatation catheter, and the guiding catheter within the coronary artery.

(emphasis added). Applicant's Specification thus indicates that those of ordinary, if not advanced, skill in the art were aware of the general teaching of advancing guidewires through catheters, but that those skilled in the art did not consider the general teaching of inserting a guidewire into

the side of a dilation catheter applicable to securing a guiding catheter in a fixed position or providing an opening in the side wall of an anchoring catheter through which a guidewire and balloon dilation/treatment catheter may extend. In response to Dr. Pierpont's awareness of the work of Dr. Crittenden, the Examiner asserts that "[t]he bottom line is that these two teachings were available to the inventor at the time of invention, and the fact that it did not occur to the inventor to make the combination until a later time does not support the assertion that the combination would not have been obvious." (Examiner's Answer, page 6, final sentence). Applicant respectfully asserts that such an assertion, made by the Examiner after the time of invention, directly assumes the result that an individual aware of the references at the time Applicant's invention was made (which, as argued above, do not meet each and every limitation of Applicant's claims) would necessarily combine the references to arrive at the Applicant's claimed invention. The Examiner's conclusion not only embodies hindsight reasoning but also is contradicted by the fact that the inventor, as one having ordinary if not advanced skill in the art, was aware of the references for years before discovering how Dr. Crittenden's teachings could be implemented on Dr. Pierpont's original device. Based upon the foregoing arguments, Appellant believes all pending claims contain allowable subject and respectfully requests allowance of the application. Additionally, claims 2 - 9 depend on claim 1 and 11 - 13 depend on claim 9, and for at least this reason are also considered in allowable form. Thus Applicant respectfully requests reversal of the rejection under 35 U.S.C. § 103.

CONCLUSION:

If any issues remain that may be expeditiously addressed in a telephone interview, the Examiner is encouraged to telephone the undersigned at 515/558-0200.

There are no fees or extensions of time believed to be due in connection with this reply; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account 50-2098.

Respectfully submitted,



Timothy J. Zarley
Reg. No. 45,253
ZARLEY LAW FIRM, P.L.C
Capital Square
400 Locust Street, Suite 200
Des Moines, IA 50309-2350
Phone No. (515) 558-0200
Fax No. (515) 558-7790
Customer No. 34082
Attorneys of Record

- TJZ/WRT/jlk -